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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,644	01/08/2002	Jacques F. Banchereau	13786-7	7691

45473 7590 11/07/2008
BRINKS, HOFER, GILSON & LIONE
2801 SLATER ROAD, SUITE 120
MORRISVILLE, NC 27560

EXAMINER	
CHANDRA, GYAN	
ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
11/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/042,644	BANCHEREAU ET AL.	
	Examiner	Art Unit	
	GYAN CHANDRA	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *99-103* is/are pending in the application.

4a) Of the above claim(s) *101 and 102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *99, 100 and 103* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/6/08; 9/10/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/10/2008 has been entered.

Status of Application, Amendments, And/Or Claims

Claims 1-98 have been cancelled. The addition of claim 103 has been made of record.

Claims 101-102 remain withdrawn for the reasons of record in pg. 2 of the office action of 3/11/2008. It is noted that the claims, as filed on 9/10/2008, do not properly identify the claim status (e.g., claims 101 and 102 must indicate as withdrawn).

Claims 99, 100 and 103 are examined on the merit to the extent that they read on the elected species psoriasis, and an antibody as the interferon antagonist.

Response to Arguments

Claim Objections-*maintained*

Claim 100 remains objected for reciting non-elected inventions (i.e., aplastic anemia, Behecet's disease.... and lupus) for the reasons of record in pg. 2 of the Office Action of 3/11/2008. Applicant argues that the objection be held in abeyance until

allowance of generic claim 99 upon which other species should be examined under 37 CFR 1.141 stated at page 2 of the Office Action of 8/23/2005. This is found persuasive.

Claim Rejections - 35 USC § 102-*withdrawn*

Applicant's arguments, see Response, filed 9/10/2008, with respect to the rejection(s) of claim(s) 99-100 under 35 U.S.C. 102(b) as being anticipated by Skurkovich et al (US Patent No. 5,888,511) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Applicants' cancellation of claims 80-81, 85-92 and 96-98; and the addition of claim 103.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 99, 100 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skurkovich (5,888,511).

The instant claims are broadly drawn to a method of treating an autoimmune disease in a subject comprising administering a composition consisting of one or more antibodies consisting of one or more humanized or human monoclonal anti-IFN-α antibodies or antigen-binding fragments thereof and a diluent, a preservative, a solubilizer, an emulsifier, an adjuvant, a carrier, a buffer, a pharmaceutical additive, a detergent, an anti-oxidant, a bulking substance, a tonicity modifier, a flavoring agent, a lubricant, a suspending agent, a filler, a glidant, a compression aid, a binder, a tablet-disintegrating agent, an encapsulating material, a sweetener, a thickening agent, a color, a viscosity regulator, a stabilizer, an osmo-regulator, a pharmaceutically acceptable propellant, a flavorant, a dye, a coating, or a combination of any thereof, wherein said autoimmune disease is not rheumatoid arthritis, Acquired Immune Deficiency Syndrome (AIDS), or diabetes (claim 99), wherein the autoimmune diseases

is psoriasis (claim 100), and wherein the autoimmune diseases is not ankylosing spondylitis (claim 103).

Skurkovich et al teach that autoimmune disease results when an individual's immune system attacks his own organs or tissues, producing a clinical condition associated with the destruction of that tissue, as exemplified by diseases such as rheumatoid arthritis, insulin-dependent diabetes mellitus, acquired immunodeficiency syndrome ("AIDS"), hemolytic anemias, rheumatic fever, Crohn's disease, Guillain-Barre syndrome, psoriasis, thyroiditis, Graves' disease, myasthenia gravis, glomerulonephritis, autoimmune hepatitis, multiple sclerosis, systemic lupus erythematosus (col. 1, lines 35+). They teach that inhibiting the immune response or removing the cause for an autoimmune disease is desirable (col. 1, lines 44-46). They teach that autoimmune diseases are connected with a disturbance in the synthesis of interferons and other cytokines induced by interferons (col. 2, lines19+). Skurkovich et al teach that IFN has been found in the circulation of patients with autoimmune diseases, and it has been neutralized in vivo with an antibody to leukocyte (alpha) IFN (IFN-α) and that healthy people do not have interferon in their blood (col. 2, lines 27+). They define the term "antibody" is intended to include monoclonal or polyclonal antibodies, or a combination thereof, humanized forms of the monoclonal antibodies (comprising only human antibody protein), and chimeric monoclonal antibodies, as well as biologically active fragments, functional equivalents, derivatives, or allelic or species variants thereof (col. 15, lines 2+). Skurkovich et al teach that techniques for preparing monoclonal antibodies are well known in the art, and they cite the references Campbell

(19840 and St. Groth (1980) to support the state of the art (col. 16, lines 4+). Skurkovich et al teach preparing a pharmaceutical composition comprising a flavoring agent, disintegrating agent, gladiant, or a sweetening agent (col. 19, lines 30+).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of invention was made to treat an autoimmune disease where interferon alpha antibody is present in the blood of a subject having said autoimmune disease by administering a monoclonal antibody against interferon-α as taught by Skurkovich et al. One would have been motivated to administer an anti-interferon α monoclonal antibody because Skurkovich et al teach that IFN has been found in the circulation of patients with autoimmune diseases and not in healthy subjects (col. 2, lines 27+). Additionally, one would have a reasonable expectation of success in treating a subject in need thereof by administering a therapeutically effective amount of a composition consisting of a monoclonal anti-IFN-α or humanized IFN-α because Skurkovich et al teach administering anti-IFN-α for treating rheumatoid arthritis (which is an autoimmune disease) (col. 24, Example 3).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra
Art Unit 1646
29 October 2008
Fax: 571-273-2922

/Robert Landsman/
Primary Examiner, Art Unit 1647